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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,950	09/25/2003	R. Eric Montgomery	P1087US02	7057

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DISCUS DENTAL, LLC
8550 HIGUERA STREET
CULVER CITY, CA 90232

EXAMINER

BUMGARNER, MELBA N

ART UNIT	PAPER NUMBER
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3732

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/670,950	Applicant(s) MONGTOMERY, R. ERIC	
	Examiner Melba Bumgarner	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20,25-42 and 51-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20,25-42 and 51-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 18, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Green (5,829,976). Green discloses a therapeutic dental delivery device comprising a liquid oral therapeutic dental composition (column 1 line 67), an applicator of a brush (column 1 line 14), an activator 32 coupled to the applicator of a push button mechanism and a reservoir 30 located in the device proximate the activator and configured to store the composition, a cap 14 having an open end terminating at a position between the activator and the applicator, the activator is configured to dispense the composition from the reservoir to the applicator. The intended use of the composition outside of the delivery device does not impose any further structural limitation on the device and is given little patentable weight, the composition is capable of increasing viscosity in the environment, even when the environment is considered “more humid” environment than an undisclosed environment.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18-20, 25, 27, 33, are 38 are rejected, in the alternative, under 35 U.S.C. 103(a) as obvious over Green in view of Ding et al. (6,541,020). Green discloses the therapeutic dental delivery device that shows the limitations as described above and the composition stored in the reservoir of the device is capable of its intended use; however, Green does not explicitly show the composition that increases in viscosity in a more humid environment. Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel (moisture or temperature responsive) composition that increase in viscosity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Green in order to have a composition that can be easily dispensed and provide controlled release of therapeutic agent in view of Ding et al. Ding et al. show the composition comprising a moisture responsive gel carrier and a therapeutic agent, and it would have been obvious matter of choice to have a compound in salt form in the composition. The gel carrier comprises polymer complex comprising carboxypolymethylene and polyvinylpyrrolidone (column 13 lines 56, 60).

5. Claims 18-20, 26, 28-30, 32, 33, 38, are 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace (1,362,937) in view of Marx (1,041,315) and further in view of Ding et al. Grace discloses a therapeutic dental delivery device comprising a dental composition (page 2 line 50), an applicator 30 of a brush, an activator coupled to the applicator of a twist mechanism and a reservoir 26 located in the device proximate the activator and configured to store the composition, the activator is configured to dispense the composition from the reservoir to the applicator; however, Grace does not show a cap. Marx teaches a dental device comprising a cap for covering the applicator having an open end. It would have been obvious to one of ordinary

skill in the art at the time the invention was made to have the device with the cap of Marx in order to protect the brush from dust and impurities in view of Marx. It would have been obvious to one of ordinary skill in the art made as to the specific activator, since interchanging of twist mechanism in the device with a push button involves only routine skill in the art and Grace suggests other mechanical embodiments. The modified device does not show composition that increases in viscosity in the environment. Ding et al. teach a liquid therapeutic composition comprising a carrier hydrogel (moisture or temperature responsive) composition that increase in viscosity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Grace and Marx in order to have a composition that can be easily dispensed and provide controlled release of therapeutic agent in view of Ding et al. Ding et al. show the composition comprising a moisture responsive gel carrier and a therapeutic agent, and it would have been obvious matter of choice to have a compound in salt form in the composition. The gel carrier comprises polymer complex comprising carboxypolymethylene and polyvinylpyrrolidone (column 13 lines 56, 60).

6. Claims 34-37, 39, 40, 42, and 51-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green in view of Ding et al. and further in view of Matthews et al. (2003/0232310). The modified device of Green and Ding et al. discloses a device that shows the limitations as described above; however, Green does not show the composition comprising therapeutic agent of peroxide. Matthews et al. teach a device comprising a liquid oral therapeutic dental composition comprising therapeutic agent of hydrogen peroxide or carbamide peroxide [0020]-[0022]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Green to have the therapeutic agent of Matthews et

al. in order to whiten or bleach one or more teeth. Matthews et al. teach having instructions in order to show how to use the composition.

7. Claims 34-37, 39, 40, 42, and 51-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Matthews et al. The modified device discloses a device that shows the limitations as described above; however, they do not show the composition comprising peroxide. Matthews et al. teach a device comprising a liquid oral therapeutic dental composition comprising therapeutic agent of hydrogen peroxide or carbamide peroxide [0020]-[0022]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device to have the therapeutic agent of Matthews et al. in order to whiten or bleach one or more teeth. Matthews et al. teach having instructions in order to show how to use the composition.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grace in view of Marx and Ding et al. and further in view of Dragan (6,929,475). The modified device discloses a device that shows the limitations as described above; however, they do not show plurality of bristles aligned generally parallel with lengthwise direction of the device. Dragan teaches a dental device comprising an applicator with plurality of bristles 246 aligned generally parallel with lengthwise direction of the device the composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device to have the applicator of Dragan in order to apply material between teeth and to gum at base of the teeth in view of Dragan.

Drawings

9. The drawings are objected to under 37 CFR 1.83(a). New figure 9 is objected to for illustration of the internal configuration that is not disclosed in the specification. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Response to Arguments

10. Applicant's arguments filed March 12, 2008 have been fully considered but they are not persuasive. With respect to the 35 USC 102 rejection that is maintained, the amendment to product claim 18 of the limitation "in a more humid environment" is a phrase of intended use in that the reservoir of the delivery device is configured to store the composition. It is noted that

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the specification states that the delivery devices of such types are known in the art (page 17) and that the dental composition can be dispensed from any suitable delivery device (page 18). It appears that the applicant is arguing that the prior art show more that what is claimed. It is believed that the prior art meet the combination of the composition with the device in that the claimed composition is required to “comprise” certain material(s). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Matthews et al. is used to show the agent in the composition that is lacking in primary references, the use of the dipping device that the applicant argues is not used in the rejection. Marx is used to show the cap that is lacking in Grace. Dragan is used to show the orientation of bristles, the dental material disposed on the device is not used in the rejection.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is 571-272-4709.

The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriquez can be reached at 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Melba Bumgarner/
Primary Examiner, Art Unit 3732